K111102
P. 1 of 3

510(k) SUMMARY MAY - 5 2011

General Information

Submitted by:	Haas Software 6233 Paso Los Cerritos San Jose, CA 95120 Phone: (888) 245-5214
Contact Person:	Eric H Smith 6233 Paso Los Cerritos San Jose, CA 95120 Phone: (888) 245-5214 Fax: (408) 378-5354
Date Prepared:	Dec 8, 2010

Device Information

Trade Name:	RadioVision
Common Name:	Picture archiving and communications system
Classification:	Class II
Classification Name:	System, Image Processing, Radiological
Reference:	21 CFR 892.2050

Predicate Device

Manufacturer: Gendex Dental Systems **Product Name: VixWin Pro**
510(k) No. K060178

Device Description

RadioVision is a Macintosh-based image management database, or system used primarily by dentists to acquire, archive, display, enhance, print, email, and import/export digital images.

Records are stored in a SQL database, searchable by any of the database table column names. The database stores basic patient information and digital image data without compression. Basic image enhancement information is also stored to the database so that the images can be

re-displayed at a later time with enhancements applied, without altering the original image data. Images may be assembled into layouts which can be customized as required.

RadioVision includes standard enhancements such as brightness, contrast, sharpening and false color. Additional advanced controls are also available such as histogram equalization and the CrystalView and Highlight filters.

RadioVision includes an automatic backup feature that allows the database to be backed up once each day at a specific time, and will create time-stamped copies of the database so that one can return to a specific point in time. RadioVision also includes the ability to restore a previously created database backup.

Intended Use

RadioVision is a Macintosh-based image management database, or system used primarily by dentists to acquire, archive, display, enhance, print, email, and import/export digital images.

Safety Information, comparison to predicate device

A Hazard Analysis was performed for RadioVision, which led to the development of Software Requirement Specifications (SRS). The SRS was used to develop a Verification & Validation (V&V) plan executed through a series of Test Cases. The V&V testing was passed, demonstrating that RadioVision performs as indicated.

	Pre-Market Notification	**Predicate Device**
	Haas Software RadioVision	**VixWin Pro**
General Information		
510(k) Number	Not yet assigned	K060178
Regulatory Classification	Class II	
Features		
Implementation	Software Only	Software Only
Host Platform	Mac OS	PC
USB Support	YES	YES
X-Ray Sensor Capture	YES	YES
Enhance Images	YES	YES
Store and Recall Image	YES	YES
Intra-Oral camera capture	YES	YES

Conclusion

The information contained in this Pre-market Notification is sufficient to demonstrate that RadioVision functions as described, and is substantially equivalent to the VixWin Pro software manufactured by Gendex Dental Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Haas Software
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

MAY - 5 2011

Re: K111102
Trade/Device Name: RadioVision
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 12, 2011
Received: April 20, 2011

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

1. Indications for Use Statement

Indications for Use Form

510(k) Number (if known): ___None_____

Device Name: RadioVision

Indications for Use:

RadioVision is a Macintosh-based image management database, or system used primarily by dentists to acquire, archive, display, enhance, print, email, and import/export digital images.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111102